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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,508	09/29/2003	Christophe Boule	016800-539	1349
21839 7590 02/14/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/671,508

Applicant(s)

BOULLE ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9,11-24,48-50,58 and 60-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,6,7,9,11-24,48-50,58,60-64 and 66-74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/3/2004 & 12/14/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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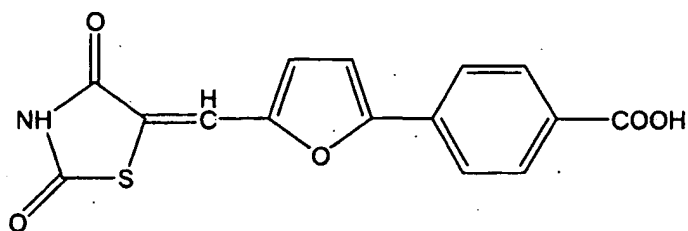
DETAILED ACTION

Claims 1, 2, 4, 6, 7, 9, 11-24, 48-50, 58 and 60-74 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (directed to method of use), and the species of Compound 1 found on page 40 of the instant specification (reproduced below), in the reply filed on November 28, 2006 is acknowledged.

Compound 1: 4-{5-[(2,4-Dioxo-1,3-thiazolidin-5-ylidene)methyl]-2-furyl}benzoic acid



The traversal is on the ground(s) that: (1) an error has been made in the class/subclass combinations; and (2) for proper restriction between patentably distinct

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inventions, the inventions must be independent or distinct and there must be a serious burden on the Examiner if restriction is not required.

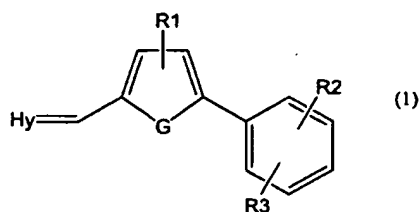
This is not found persuasive. Applicant is correct, in-part, that the classifications given in the Restriction Requirement are not correct if one were to classify the formula (I) core irrespective of the heterocyclic defined by the variable Hy. Groups I-III would be classified as follows:

- I. Claims drawn to methods of using products of Formula (I) wherein G is O, classified in class 514, subclass 461+.
- II. Claims drawn to methods of using products of Formula (I) wherein G is S, classified in class 514, subclass 444.
- III. Claims drawn to methods of using products of Formula (I) wherein G is NH, classified in class 514, subclass 422.

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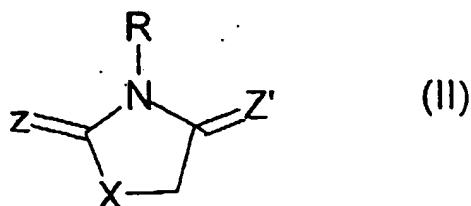
Note, Group I has been classified as 514/461+, the plus sign meaning other subclasses following 461 are also possible searches.

However, since the definition of the Hy variable in the independent claims was so broad {i.e., 4, 5, 6 or 7 membered heterocycles}, the various preferred embodiments (i.e., heterocycle of formula II as found on pages 18-19), the various formulas (i.e., pages 21 and 24) and examples (starting on page 40) in specification were reviewed. The general areas of classification given in the Restriction Requirement were based on the following compounds of formula (I)



wherein Hy was a heterocyclic ring of formula (II), as found in the preferred embodiments and the examples in the specification.

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X is S, O or NH

The three heterocyclic rings embraced by formula (II) are thiazolidine, oxazolidine and imidazolidine.


By the classification hierarchy, the heterocyclic ring of formula (II), not the heterocyclic ring defined by the G containing ring, controls where the compounds are classified. The Examiner chose not to restrict the claims based on the three heterocyclic rings embraced by formula (II), which would require the presence of two carbonyl and/or thiocarbonyl groups as well as their specific orientation. Only the general starting areas for each of the three heterocyclic rings of formula (II) were given in the Restriction Requirement.

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Note, each Group has been classified having a plus sign and the plus sign meaning other subclasses following are also possible searches.

In view of Applicant's arguments, an attempt was made to examine the full scope of compounds of instant formula (I). However, with the definition of the Hy variable being so broad {i.e., 4, 5, 6 or 7 membered heterocycles}, the structure search on STN.CAS ONLINE would not run to completion (only 1.4% processed in sample search, online and batch found "INCOMPLETE"). See a partial reproduction of the transcript from this attempt.

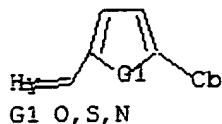
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 671508-2.trn

=> d l1

L1 HAS NO ANSWERS

L1 STR



Structure attributes must be viewed using STN Express query preparation.

=> s l1

SAMPLE SEARCH INITIATED 07:03:35 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 138558 TO ITERATE

1.4% PROCESSED 2000 ITERATIONS

11 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE **INCOMPLETE**

BATCH **INCOMPLETE**

PROJECTED ITERATIONS: 2749174 TO 2793146

PROJECTED ANSWERS: 13585 TO 16897

L3 11 SEA SSS SAM L1

As for the serious burden, separate search considerations are involved for each group. There may be some overlap in the class/subclass search. However, there would also be a mandatory search of the core structure of Formula I, where G is O, S or NH. Therefore, it would impose an undue burden on the

Examiner and the Patent Office's resources if the instant application were unrestricted.

As noted above, the Examiner has required election and Applicant has properly and timely elected. However, the Examiner is cognizant that election along some other line(s), and still afford a balance between the Applicant's claims and resources of the Patent Office could be possible. Hence, in Applicant's consideration for response to this Office Action, if Applicant desires to provoke an interview to discuss some other mode of, or groupings of, patentable distinct subject matter, the Examiner is certainly amenable to such a discussion. In such an event, it is suggested that such be scheduled timely and before Applicant makes written response as the Examiner must act on any "amended" case within two months of receipt of the response. The above requirement is the present way the Examiner would make the requirement, however, such a mode is not fixed in concrete and is subject to

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revision so long as to ultimate conclusion is that patentably distinct subject matter is involved in the different inventions.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group I is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 28, 2006.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a) - (d), which papers have been placed of record in the file.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on June 3, 2004 and December 14, 2006.

Claim Objections

Claims 1, 2, 4, 7, 9, 12, 49, 50, 58, 63 and 68 are objected to because of the following informalities.

a) In claim 1, under the definition of H_y , R' is listed twice as a possible substituent on an alkyl (page 3, lines 3-4 of the Amendment filed November 28, 2006). See claims 2, 4, 7, 9, 49, 50, 58 and 68 for same.

b) In claim 1, under the definition of R_1 , R_2 and R_3 , R_0' is listed twice as a possible substituent on an alkyl (page 3, line 17 of the Amendment filed November 28, 2006). See claims 2, 4, 7, 9, 49, 50, 58 and 68 for same.

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c) Claim 12 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period.

d) In claim 63, a space is needed after Z' (second occurrence).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 65, it is unclear what is meant by the "analogues" of cyclosporins and therefore, the metes and bounds of the claim cannot be ascertained.

Allowable Subject Matter

The elected method of using the elected species of Compound 1, found on page 40 of the instant specification, is allowable over the art of record.

Claims 1, 2, 4, 6, 7, 9, 11-24, 48-50, 58, 60-64 and 66-74 are objected to for reasons stated above and containing non-elected subject matter. Claims presented directed solely towards the elected invention would appear allowable over the art of record.

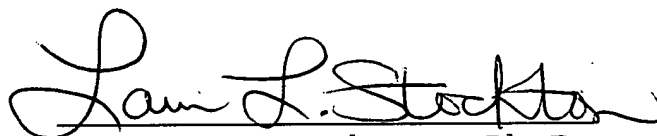
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

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PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

February 7, 2007